REMARKS

Claims 1 has been amended to correct a typographical error, so that it is limited to water soluble porous bodies, and to specify that a water-insoluble material is incorporated into said lattice to be dispersed when the water-soluble porous body dissolves. The porous body is clarified to be a water-soluble lattice containing a water-insoluble "payload" material, as distinguished from the cited art.

Claim 1 has been further amended to incorporate the subject matter of claim 3, which has been canceled, without prejudice.

Claim 4 has been amended to depend on the amended claim 1.

Claim 11 has been amended to specify that a water soluble polymeric material other than a surfactant is used, similarly to the limitation of claim 1. Support for this subject matter may be found throughout the Specification.

Care has been taken not to introduce any new matter.

The Present Invention

The present invention relates to water soluble or dispersible porous bodies and to methods of producing such porous bodies.

Terminal Disclaimer Obviates Double Patenting

Claims 1-22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/587,734 and Claims 1-3, 5, 8-14, 16 and 18-20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-10 and 12-18 of copending Application No. 10/587,722. While respectfully traversing due to claim differences, especially in view of the present amendments, applicants submit a corrected terminal disclaimer in the effort to expedite the prosecution of the present case to issuance without delay.

Clarity / Indefiniteness

The Examiner has rejected claims 1 and 11 for failing to particularly point out and distinctly claim the subject matter regarded as the invention. More particularly, the Examiner considers that the scope of claims 1 and 11 is unclear because a person skilled in the art could not determine whether component (c) (i.e. the water-insoluble material) is incorporated in the porous bodies as part of the lattice or whether components (a) and (b) (i.e. the water-soluble polymeric material and surfactant) form the lattice with component (c) being contained within the lattice.

Applicants respectfully submit that components (a) and (b) form the lattice and component (c) is contained within the lattice. This is described at page 2, lines 16 to 27 of the present application as originally filed (which makes it clear that the lattice comprises components (a) and (b)) and at page 6, lines 21 to 23 of the present application as originally filed.

The Examiner also objects to the wording in claims 1 and 11 that specifies that component (c) is incorporated into the lattice to be dispersed when the water-soluble porous body dissolves. According to the Office Action, this implies that the water-insoluble material will only be incorporated into the lattice after dissolution of the porous body and has stated that the lattice will dissolve when the porous body dissolves, since

the porous body is comprised of the lattice.

Applicants respectfully submit that the porous bodies comprise a lattice made from components (a) and (b) and component (c) is contained within the lattice. When the porous bodies are exposed to an aqueous medium, the lattice dissolves and the water-insoluble material (i.e. component (c)) is dispersed. This is described at page 2, line 29 to page 3, line 2 and page 6, lines 16 to 19 of the present application as originally filed, which makes it clear that the water-insoluble material is dispersed when the carrier/surfactant dissolves.

Claims Are Not Obvious under 35 USC § 103

Claims 1, 3-8, and 10-21 (all the claims being considered) were rejected under 35 U.S.C. 103(a). Claim 22 had been previously canceled. Claim 3 has been canceled after incorporation of its subject matter in claim 1. Applicants respectfully traverse.

Fujimoto et al.

The Examiner has rejected claims 1, 3, 4, 11, 13, 16 and 20-21 for being obvious over the disclosure of Fujimoto *et al.* (Abstract of JP-01011141). According to the Office Action, the porous article of Fujimoto is water soluble and that is sufficient to render the present invention obvious. Applicants respectfully traverse.

Fujimoto *et al.* discloses a porous article of a hydrophilic polymer. The porous article is made by providing an aqueous solution, a uniform aqueous suspension or a mixture thereof of a hydrophilic polymer and a surfactant and then freezing and drying the solution, suspension or mixture so as to obtain the porous article.

The porous article disclosed in Fujimoto *et al.* does not comprise a water-

insoluble material incorporated into a lattice to be dispersed when the article dissolves. Additionally, in relation to claim 11 in particular, in Fujimoto *et al.* an aqueous solution or suspension is used in the preparation of the porous article, not an oil-in-water emulsion as required by claims 11 to 20. These distinguishing features are not taught or suggested in Fujimoto *et al.*, such that the claimed subject matter is non-obvious over the disclosure of this document.

Additionally, the Office Action acknowledges that Fujimoto et al. do not disclose that the polymeric compositions have an intrusion volume as claimed.

Wu et al. (US-5,025,004) and Kitagawa (US-6,048,908)

The Examiner has rejected claims 1, 3 to 8 and 10 for being obvious over the disclosures of Wu *et al.* (US-5,025,004) and Kitagawa (US-6,048,908) in combination. According to the Office Action, as to claim 1, Wu, et al., teach a process for preparing solid, powdered, polymeric compositions (column 3, lines 6-8), comprising at least one polymeric, water soluble or water dispersible, nonionic emulsifier (column 3, lines 51-53) in an amount of from 0.5 to 70% (column 4, lines 17-18), an additive in an amount from 10 to 25% weight which can include surfactants such as Tween 80; The powders taught by Wu, et al., have a particle size in the range of from 10 µm to 30 µm (meaning the particles are not spheres with a diameter of from 0.2 to 0.5 mm) (column 8, lines 37-39).

The Office Action acknowledges that Wu, et al., fail to explicitly teach that the polymeric compositions have an intrusion volume as measure by mercury porosimetry of at least about 3 mL/g. Further, the Office Action acknowledges that Wu, et al., do not specify that the powdered polymeric materials are porous.

Further according to the Office Action, as to claims 3-4, Wu, et al., teach the process for preparing the composition as applied to claim 1, wherein the polymeric materials can comprise cellulose acetate phthalate which the Office Action asserts is

water soluble.; As to claims 5 and 7, Wu, et al., teach the process for preparing a composition as applied to claim 1 in which the surfactant is nonionic Tween 80, polyethylene glycol sorbitan monoleate (column 8, line 60).

The Office Action acknowledges, as to claim 6, Wu, et al., do not specify that the surfactant used in the invention is solid at ambient temperature.

However, Kitagawa is cited for the use of distearate as a surfactant which is solid at room temperature (column 8, lines 52-54).

Further according to the Office Action, as to claim 8, Wu, et al., teach the process for preparing the composition as applied to claim 1, further comprising at least one water insoluble polymer (column 8, lines 25-26) and a water soluble polymers (column 8, lines 56-59).; Wu, et al., further teach dispersing the powdered, polymeric composition into an aqueous solution (column 8, lines 45-46).; etc.

Wu *et al.* discloses powdered, polymeric compositions and processes for preparing them. The process comprises the step of preparing an oil-in-water emulsion by contacting an organic (oil) phase with water. The organic phase is prepared by contacting an organic solvent system with a combination of surfactants. The organic solvent system comprises at least one water-insoluble polymer and at least one water-immiscible organic solvent (e.g. oil). The combination of surfactants comprises at least one polymeric oil-in-water emulsifier and at least one water-in-oil emulsifier. The emulsion formed is passed through a particle size reduction means and then the organic solvent is removed from the emulsion to form an aqueous colloidal dispersion of the water-insoluble polymer. The aqueous colloidal dispersion is then dried to form a water-dispersible powder. Wu *et al.* teaches that the compositions may further comprise coating additives, such as Tween (see column 3, lines 5 to 25, column 3, line 37 to column 4, line 21, column 8, lines 36 to 38 and 51 to 66 and claim 1 of Wu *et al.*).

The Examiner has stated that the powdered polymeric compositions of Wu *et al.* must have an intrusion volume as defined in claim 1 of the present application because, in his view, they are equivalent to the porous bodies as defined in claim 1 of the present application. This is incorrect, as discussed further below.

The Examiner has referred to Kitagawa as apparently teaching the preparation of microbeads and seems to consider that it would have been obvious to the skilled person reading Wu *et al.* and Kitagawa in combination to provide porous bodies. Again, Applicants respectfully traverse.

The porous bodies defined in claim 1 of the present application are distinguished over the powdered, polymeric compositions disclosed in Wu *et al.* for a number of reasons.

The compositions of Wu *et al.* do not comprise water-soluble porous bodies comprising a three-dimensional oil and water emulsion templated open-cell lattice. In the process of Wu *et al.*, an aqueous colloidal dispersion of a water-insoluble polymer is formed, which dispersion is dried, for example by spray-drying or freeze-drying. The aqueous colloidal dispersion of the water-insoluble polymer is a latex (i.e. a stable dispersion/emulsion of polymer microparticles in an aqueous medium) and when the latex is dried a powder is produced. This powder is not the same as the porous bodies defined in claim 1 of the present application where the pores are derived from the oil phase of the emulsion.

Furthermore, **the powders of Wu *et al.* are not water-soluble**. Wu *et al.* teaches that the powders it discloses may be dispersed in water with mild agitation (see column 3, lines 20 to 24 of Wu *et al.*). Thus, Wu *et al.* also does not disclose porous bodies comprising a water-insoluble material that is dispersed when a water-soluble porous body (within which the water-insoluble material is contained) dissolves. Additives can be present (and these can include water soluble polymers - see column 8, line 56 ff), but these are only present at low levels. In relation to water-solubility, the

Examiner has stated that the powdered compositions of Wu *et al.* must be water-soluble because they may comprise cellulose acetate phthalate. However, note that cellulose acetate phthalate is listed at column 6, line 7 of Wu *et al.* as an example of a water-insoluble polymer. Given that Wu do not disclose the same materials, one of ordinary skill could not reach the conclusion that, as the bodies dissolve (which they do not), they would release the water-insoluble material incorporated into the lattice.

Additionally, the Examiner seems to consider that the oil-in-water polymeric emulsifier of Wu *et al.* (see column 3, lines 51 to 53 of Wu *et al.*) corresponds to component (a) of claim 1 of the present application. This is not the case. An emulsifier is a surfactant. Component (a) of claim 1 of the present application is a water-soluble polymeric material other than a surfactant. Thus, the powdered, polymeric compositions of Wu *et al.* do not comprise a water-soluble polymeric material other than a surfactant.

Finally, Wu *et al.* also does not disclose an extrusion volume as defined in claim 1 of the present application, as acknowledged by the Examiner. Thus, Applicants respectfully submit that the porous bodies defined in claim 1 of the present application are distinguished over the powdered polymeric compositions disclosed in Wu *et al.* for a plurality of reasons and that there is no teaching in Wu *et al.* that would have led the skilled person to modify the powdered polymeric compositions it discloses so as to have arrived at the porous bodies as defined in claim 1 (and the claims dependent thereon).

Kitagawa fails to provide any teaching that, in combination with Wu *et al.*, would have led or even motivated the skilled person to have provided the water-soluble porous bodies defined in claim 1 (and the claims dependent thereon).

Kitagawa discloses porous cross-linked hydrophilic polymeric microbeads and relates to cross-linked, insoluble particles formed by emulsion-templating. The cross-linked polymeric emulsion templated microbeads disclosed in Kitagawa are not water-

soluble or dispersible in the sense of the present invention. This is evidenced throughout Kitagawa. For example, at column 2, lines 60 to 67 of Kitagawa there is a discussion of the water-absorbing properties of the microbeads and their suitability for a number of applications in which aqueous fluids are absorbed. Figures 1b and 3b of Kitagawa show a cross-linked polymer microbead in a water saturated state, further confirming that these are not water-soluble particles. Example 6 of Kitagawa discusses the uptake of saline solution by immersed microbeads (which do not dissolve; see column 27, lines 20 to 52 of Kitagawa). Example 7 of Kitagawa shows that a relatively low level of cross-linking will lead to a microbead that is water-insoluble and can take up aqueous solutions. The degree of uptake is related to the degree of cross-linking (see column 28, lines 58 to 60 of Kitagawa). Example 1 of Kitagawa (see column 16, lines 16 to 18 of Kitagawa) shows that at as low as 2.44% cross-linking beads are obtained which will swell in water rather than dissolving.

In his comments on our arguments made previously, the Examiner has stated that he has disregarded our comments on Kitagawa set out above because, in his view, the microbeads disclosed in Kitagawa must be capable of dissolving in view of the reference in Kitagawa to the use of the microbeads as carriers to provide sustained release of an agent (see column 14, line 66 to column 15, line 8 of Kitagawa). The Office Action position notwithstanding, Applicants respectfully submit that, of course, the microbeads disclosed in Kitagawa may release an agent, such as a fragrance, without a lattice dissolving.

Thus, Kitagawa does not provide the teaching that is missing from Wu *et al.* that would have been required to have arrived at the presently claimed porous bodies. In particular, Kitagawa does not disclose or suggest providing water-soluble porous bodies or a water-soluble lattice that dissolves upon contact with aqueous media so as to release and disperse a water-insoluble material.

Moreover, Kitagawa teaches away from the present invention. Kitagawa,

discloses crosslinked particles of the polymerised "high internal phase" emulsion type. These are otherwise known as polyHIPE materials and are well known and used as "super-adsorbers" in all sorts of applications due to their high capacity for adsorbing and retaining liquids. If they dissolved, they would not be much good for this.

Accordingly, claim 1 and the claims dependent thereon are non-obvious over the disclosures of Wu *et al.* and Kitagawa in combination.

Wu et al,. Kitagawa and Montforte et al. (US-3,551,522)

The Examiner has rejected claim 11 (and apparently claims 12 to 21) for being obvious over the disclosures of Wu *et al.*, Kitagawa and Montforte *et al.*, (US-3,551,522) in combination.

According to the Office Action, as to claim 11-12, Wu, et al., teach preparing solid, powdered, polymeric compositions (column 3, lines 6-8), comprising at least one polymeric, water soluble or water dispersible, nonionic emulsifier (column 3, lines 51-53) in an amount of from 0.5 to 70% (column 4, lines 17-18) and additionally comprising an additive in an amount form 10 to 25% weight which can include surfactants such as Tween 80 (column 8, lines 51-60).; Wu, et al., further teach that the composition contains at least one water-in-oil emulsifier (column 3, lines 50-68).; Wu, et al., further disclose that the composition comprises an organic solvent (liquid medium) (column 3, lines 44-48). ; Wu, et al., teach passing the polymer solution-in-water emulsion through a particle size reduction means such that the polymer is in the form of droplets having an average size in the range of about 0.1 to 0.8 µm, followed by removing the organic solvent to form aqueous dispersion, and drying the dispersion to form the water dispersible powder (column 4, lines 45-62). Wu, et al., teach drying the particles by freeze drying (column 8, lines 17-20).

The Office Action acknowledges that neither Wu, et al., nor Kitagawa teach the steps of freeze drying the porous materials.

However, according to the Office Action, one of ordinary skill in the art would recognize that freeze drying employs a fluid freezing medium used to rapidly freeze a composition and further employs drying by sublimation.; Monforte, et al., teaches breaking up a solute material into fine droplets, rapidly freezing the droplets to prevent coalescence (freeze-drying) and removal of the solvent by sublimation (column 1, lines 46-54). ; The dried droplets of Monforte, et al., are porous (column 1, lines 57).

Further according to the Office Action, as to claim 13, Wu, et al., teach the process for preparing the composition as applied to claim 1, wherein the polymeric material can comprise cellulose acetate (column 6, lines 11).; As to claims 14 and 16-17, Wu, et al., teach the process for preparing a composition as applied to claim 1 in which the surfactant is nonionic Tween 80, polyethylene glycol sorbitan monooleate (column 8, line 60).

The Office Action acknowledges, as to claim 15, Wu, et al., do not specify that the surfactant used in the invention is solid at ambient temperature.

However, Kitagawa is cited for the use of distearate as a surfactant which is solid at room temperature (column 8, lines 52-54).

Further according to the Office Action, as to claims 18-19, Wu, et al., and Kitagawa teach the polymeric compositions as applied to claim 11. ; Kitagawa teaches porous hydrophilic microbeads, produced using a formulation which comprises from 0.5 to 50% by weight monomer (column 7, lines 53-56) and 1 to 30% weight of surfactant (column 9, lines 4-8), said microbeads of which are used for drug carriers (column 15, lines 3-7).; Kitagawa further teaches that the discontinuous oil phase can be about 10%, about 20%, about 30%, about 40%, about 50% or about 60%, and as high as 99% of the emulsion (column 11, lines 38-50).; As to claim 20, Wu, et al., and Kitagawa

teach the polymeric compositions as applied to claim 11 which further comprises solvents including alicyclic hydrocarbons, ethers, and esters (column 5, lines 31-43).; As to claims 21-22, Wu, et al., teach the composition as applied to claim 11 and further teach dispersing the powdered, polymeric composition into an aqueous solution (column 8, lines 45-46).; It would have been obvious for one of ordinary skill in the art to combine Wu, et al., and Kitagawa because both disclose compositions comprising acrylate polymers (Kitagawa, column 7, lines 27-28; Wu, et al., column 6, line 29) and surfactants (Kitagawa, column 8, lines 54; Wu, et al., column 8, line 60) to make hydrophilic, water dispersible products used in pharmaceuticals (Kitagawa, column 15, lines 4-6; Wu, et al., column 3, lines 6-9).

In sum, according to the Office Action, Wu *et al.* and Kitagawa disclose all of the steps of the method of claim 11 of the present application except the freeze-drying step, which is taught in Montforte. Montforte discloses a method for making high impact polymer compositions (see column 1, lines 23 to 25 of Montforte) and seems to have been cited by the Examiner as being a general disclosure of freeze-drying.

Applicants respectfully traverse.

Applicants respectfully submit that, Montforte does not add anything significant to the teaching of Wu *et al.* and Kitagawa that would have been required to have arrived at the method as defined in claim 11 of the present application. As discussed above, Wu *et al.* does not disclose or suggest a method for preparing water-soluble porous bodies comprising a three-dimensional oil and water emulsion templated open-cell lattice. There is no teaching in Wu *et al.* as to how to provide water-soluble materials/bodies, nor is there any teaching as to how to provide a three-dimensional oil and water emulsion templated open-cell lattice. Additionally, there is no teaching or suggestion in Wu *et al.* to provide materials/bodies comprising a water-soluble polymeric material other than a surfactant. Furthermore, neither Kitagawa nor Montforte provides any such teaching.

Accordingly, claim 11 and the claims dependent thereon are non-obvious over the disclosures of Wu *et al.*, Kitagawa and Montforte in combination.

CONCLUSION

Reconsideration of the rejection is respectfully requested in view of the above claim amendments and remarks.

It is respectfully requested that the application be allowed to issue.

If a telephone conversation would be of assistance, Applicant's undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,

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